



Disclosure Statements

I have the following relevant relationships in the products or services described, reviewed, evaluated or compared in this presentation.

Hanger Clinic

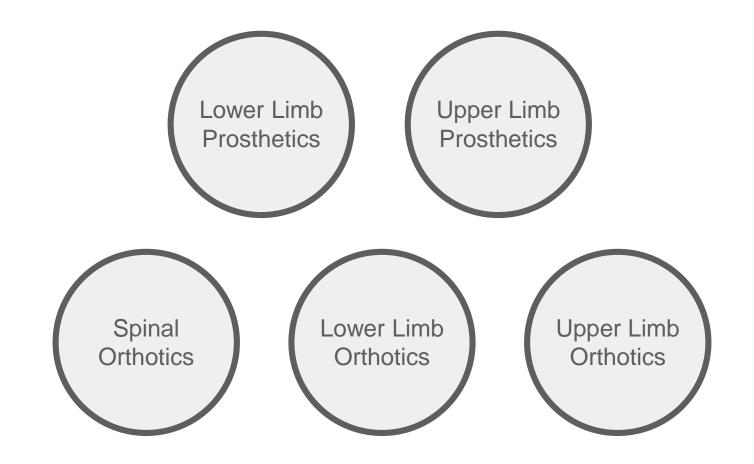
 Our moderator and prosthetist joining us today are paid employees of Hanger Clinic.

Other Disclosures (if any):

None



Hanger Clinic Continuing Education Program





Learning Outcomes

Upon completion of this presentation the participant will be able to:

- Identify trends in adult limb loss populations
- Demonstrate the value in a health care team approach to limb loss patient care
- Communicate the benefits of using outcome measures with lower limb prosthetic patients
- Discuss the Prosthetics Limb User Survey of Mobility (PLUS-MTM) assessment
- Review sample patient case studies and best practice approach to rehabilitation and a successful care plan



- Patient Profiles: What we know and how to work together
- Lower limb prosthetic outcomes and PLUS-MTM tool
- Practice: Case studies and learn how a prosthetic company is translating data into clinical care
- Discussion

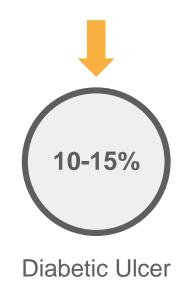




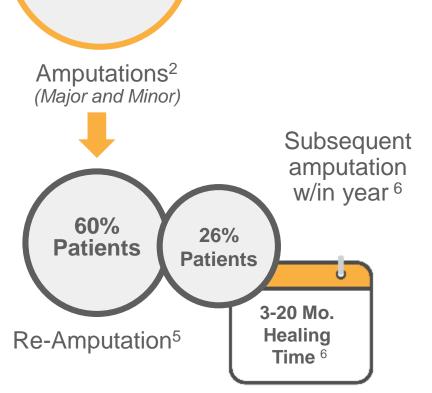
73,000

29 Million People

Diabetes Population^{1,3,4}



Vascular Population



Ziegler-Graham, K. Archives of Physical Medicine and Rehabilitation (2008) Further Citations in Reference List (see subscript)

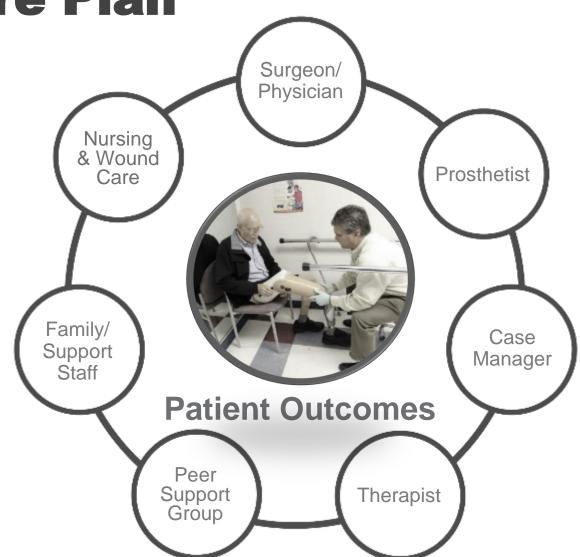


Limb Loss Patient Population: 2 Million

Trauma Population

- More than 30,000 traumatic amputations yearly
- The 3 most common mechanisms of injury are crush, guillotine and avulsion
- Approximately 80% are male
- Majority are between the ages of 15-40
- Typically are in overall good health







Why Track Mobility Outcomes: More Consistent Care

START OF EPISODE CARE



 Assess patient's current mobility

2 WEEKS AFTER PROSTHETIC DELIVERY



 Assess immediate impact of prosthetic care

EVERY 6 MONTHS



- Assess long term impact of our care
- Continuously monitor patient's mobility
- Early, proactive intervention when needed

Outcome Measures: PLUS-MTM and Prosthetic Evaluation Questionnaire





Lower Limb Prosthetic Outcomes

WHAT:

- Prosthetics Limb Users Survey of Mobility (PLUS-MTM)
- Self-reported instrument to measure mobility of adult with lower limb amputation
- Intended use: research and clinical care
- Uni/bi-lateral, various levels, current prosthesis users, <u>></u>18

WHO:

- University of Washington Center on Outcomes Research in Rehabilitation
- National Institutes of Health
- Prosthetics Research Study

ons as if you then, or walker to complete the complete the without any difficulty	to perform to			
any	a little	some	much	
(5)	(4)	(3)	(2)	(1)
(5)	(4)	(3)	(2)	(1)
(5)	(4)	(3)	(2)	(1)
(5)	(4)	(3)	(2)	(1)
(5)	(4)	(3)	(2)	(1)
	(5)	(5) (4) (5) (4)	(5) (4) (3) (5) (4) (3)	(5) (4) (3) (2) (5) (4) (3) (2)



PLUS-M™: Valid and Reliable

- Valid and Reliable: what and how
- Rigorously developed using modern psychometric methodology
- Numerous publications and abstracts

	0:		_	Date:					
instructions: Please respond to all questions as if you were wearing the prosthetic leg(s) you use mostays. If you would normally use a cane, crutch, or walker to perform the task, please answer the questions is if you were using that device. Please choose "unable to do" if you: Would need help from another person to complete the task, Would need a wheelchair or scooter to complete the task, or Feel the task may be unable for you Please mark one box per row.									
	Question	Without With any a little difficulty difficulty		With some difficulty	With much difficulty	Unable to do			
	Are you able to walk a short distance in your home?	(5)	(4)	(3)	(2)	(1)			
	Are you able to step up and down curbs?	(5)	(4)	(3)	(2)	(1)			
	Are you able to walk while carrying a shopping basket in one hand?	(5)	(4)	(3)	(2)	(1)			
	Are you able to keep walking when people bump into you?	(5)	(4)	(3)	(2)	(1)			
	Are you able to keep up with others when walking?	(5)	(4)	(3)	(2)	(1)			
6.		(5)	(4)	(3)	(2)				



PLUS-M™: Validation Study

The PLUS-MTM was validated against established measures of physical function, mobility and balance and was correlated with:

- Amputee Mobility PredictorTM (AMP)
- Timed Up and Go (TUG)
- PEQ-MS
- ABC
- PROMIS-PF

The PLUS-MTM

- Intra-class coefficient (ICC) greater than 0.9
- Indicating appropriate use for individual level monitoring of patients
- Better than many other patient-report instruments including the ABC, PROMIS and PEQ-MS



Scoring the PLUS-M™ 12-Item Short Form

PLUS M™ short forms are scored with a <u>T.score</u>. To find the T.score, sum scores for all responses on the short form. This is the <u>raw score</u>. Do not use the raw score for any purpose other than to look up the T.score using the conversion table below. If any questions on the short form are <u>unanswered</u>, refer to the PLUS-M™ Short Form Users Guide for instructions on scoring incorrective short forms.

PLUS-M™ 12-Item Short Form (v1.2) T-score Conversion Table

Record the PLUS-M™

T-score here

				 	fried :	nej i dedite delli		
Kow Score	T-score	SE	Percentile	Kaw Score	T-score	SE	Percentile	
12	21.8	4.4	0.2%	37	45.2	1.9	31.5%	
13	25.2	3.4	0.7%	38	45.8	1.9	33.7%	
14	27.2	3.1	1.1%	39	46.4	1.9	36.1%	
15	28.7	2.9	1.6%	40	47.1	1.9	38.5%	
16	30.0	2.7	2.3%	41	47.7	1.9	41.1%	
17	31.2	2.5	3.0%	42	48.4	1.9	43.7%	
18	32.2	2.3	3.8%	43	49.1	2.0	46.4%	
19	33.2	2.2	4.8%	44	49.8	2.0	49.1%	
20	34.1	2.1	5.5%	45	50.5	2.0	51.9%	
21	34.9	2.1	6.5%	46	51.2	2.0	54.6%	
22	35.6	2.0	7.6%	47	52.0	2.1	57.8%	
23	36.4	2.0	8.6%	48	52.7	2.1	60.8%	
24	37.1	1.9	9.8%	49	53.6	2.1	63.9%	
25	37.7	1.9	11.0%	50	54.4	2.2	67.0%	
26	38.4	1.9	12.3%	51	55.3	2.3	70.2%	
27	39.0	1.9	13.6%	62	56.3	2.4	73.4%	
28	39.7	1.9	15.1%	53	57.3	2.5	76.7%	
29	40.3	1.9	16.6%	54	58.4	2.6	79.9%	
30	40.9	1.9	18.1%	55	59.8	2.8	83.2%	
31	41.5	1.9	19.8%	56	61.0	2.9	88.4%	
32	42.1	1.9	21.5%	57	62.5	3.1	89.5%	
33	42.7	1.9	23.3%	58	64.5	3.3	92.6%	
34	43.3	1.9	25.2%	59	67.1	3.8	95.6%	
36	43.9	1.9	27.2%	60	71.4	4.9	90.4%	
36	44.5	1.9	29.3%					

For T-scores with standard error (SE) greater than 3.0, use of the PLUS-M™ CAT (www.ska-m.org) is recommended to obtain better measurement precision. Per termile indicates the percent of the PLUS-M™ development sample that reported bear mobility than as self-ended by the consexponding T-Score. For more information on interpretation of PLUS-M™ T-scores, please refer to the PLUS-M™ Short Form Users Cuide.

PLUS-MTM: T-Score

- What is it?
- How it works
- What does the output look like?
- T-Score and Medical Records

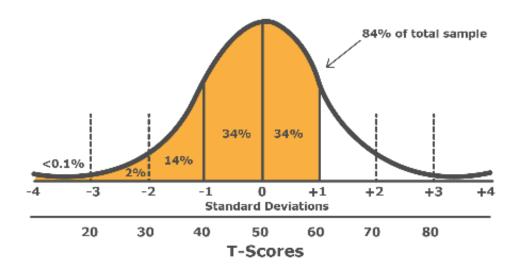


Figure 1 - A PLUS M[™] T-Score of 60 indicates that approximately 84 percent of persons in the development sample reported lower mobility, as reflected by the shaded area.



Scoring the PLUS-M™ 12-Item Short Form

PLUS M™ short forms are scored with a <u>Licone</u>. To find the Tiscore, sum scores for all responses on the short form. This is the <u>raw score</u>. Do not use the raw score for any purpose other than to look up the Tiscore using the conversion table below. If any questions on the short form are <u>unanswered</u>, refer to the PLUS-M™ Short Form Users Guide for instructions on scoring accomplishs short forms.

PLUS-M™ 12-Item Short Form (v1.2) T-score Conversion Table

	U-0-MI	12.	item one	 FOIIII	(41.5) 1	-300	ie Colive
Kew Score	T-score	SE	Percentile	Kaw Score	T-score	SE	Percentile
12	21.8	4.4	0.2%	37	45.2	1.9	31.5%
13	25.2	3.4	0.7%	38	45.8	1.9	33.7%
14	27.2	3.1	1.1%	39	46.4	1.9	36.1%
15	28.7	2.9	1.6%	40	47.1	1.9	38.5%
16	30.0	2.7	2.3%	41	47.7	1.9	41.1%
17	31.2	2.5	3.0%	42	48.4	1.9	43.7%
18	32.2	2.3	3.8%	43	49.1	2.0	46.4%
19	33.2	2.2	4.6%	44	49.8	2.0	49.1%
20	34.1	2.1	5.5%	45	50.5	2.0	51.9%
21	34.9	2.1	6.5%	46	51.2	2.0	54.8%
22	35.6	2.0	7.6%	47	52.0	2.1	57.8%
23	36.4	2.0	8.6%	48	52.7	2.1	60.8%
24	37.1	1.9	9.8%	49	53.6	2.1	63.9%
25	37.7	1.9	11.0%	50	54.4	2.2	67.0%
26	38.4	1.9	12.3%	51	55.3	2.3	70.2%
27	39.0	1.9	13.6%	62	56.3	2.4	73.4%
28	39.7	1.9	15.1%	53	57.3	2.5	76.7%
29	40.3	1.9	16.6%	54	58.4	2.6	79.9%
30	40.9	1.9	18.1%	55	59.8	2.8	83.2%
31	41.5	1.9	19.8%	56	61.0	2.9	88.4%
32	42.1	1.9	21.5%	57	62.5	3.1	89.5%
33	42.7	1.9	23.3%	58	64.5	3.3	92.6%
34	43.3	1.9	25.2%	59	67.1	3.8	95.6%
36	43.9	1.9	27.2%	60	71.4	4.9	90.4%
36	44.5	1.9	29.3%				

Record the PLUS-M[™] T-score here.

4444

PLUS-M™ T-score

For T-scores with standard error (SE) greater than 3.0, use of the PLUS-M™ CAT (www.ska-m.org) is recommended to obtain better measurement precision. Percentile indicates the percent of the PLUS-M™ development sample that reported lower mobility than is sufficiently by the convexponding T-Score. For more information on interpretation of PLUS-M™ T-scores, please refer to the PLUS-M™ Short Form

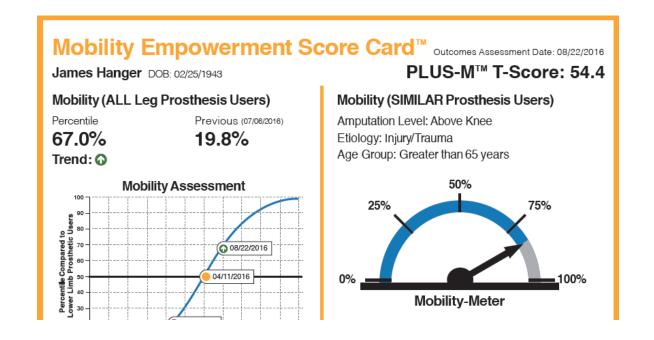


Prosthesis Evaluation Questionnaire – Well Being Subsection

- Development: Prosthetics Research Study
- Support for PEQ provided by US Department of Veterans Affairs
- Questionnaire divided into groups: Well-Being Subsection

Satisfaction
Quality of Life
8/10

Scoring is based on PRS coding and scale



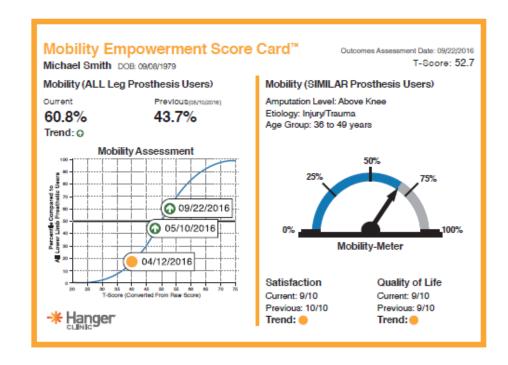
Translating data to clinical care by a large prosthetic company





Mobility Empowerment Score Card: Tracking Mobility Sample

- Measures mobility utilizing PLUS-MTM
- Tracks each patient's ME score overtime
- Monitors patient's care satisfaction (PEQ)
- Patients are advised on their progress



Tracking Mobility Sample

Practice



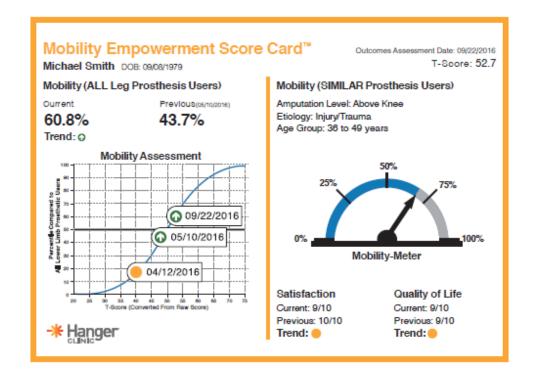


Case Studies: Transforming Patient Care

Outcomes Tracking Establishes Baseline For Mobility Improvements

Sample Case Study:

- Young traumatic patient
- Reports below average mobility at evaluation for socket replacement
- Receives new socket
- Improvements after 2 weeks
- 6 month follow-up



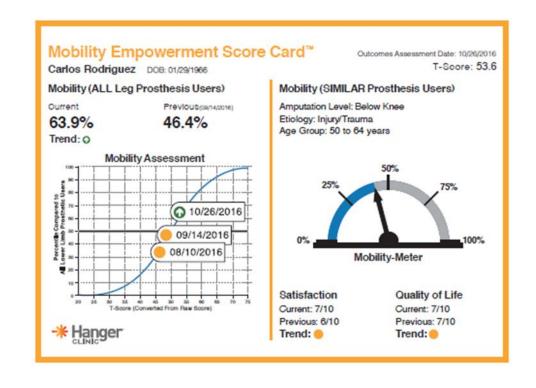


Case Studies: Transforming Patient Care

Assessment Improves Care And Results In Higher Mobility

Sample Case Study:

- Age: 50 to 64
- Etiology: Trauma
- Clinician observes issue requiring referral to PMR for eval
- Patient returned 914 with Rx for replacement
- Post-delivery appointment



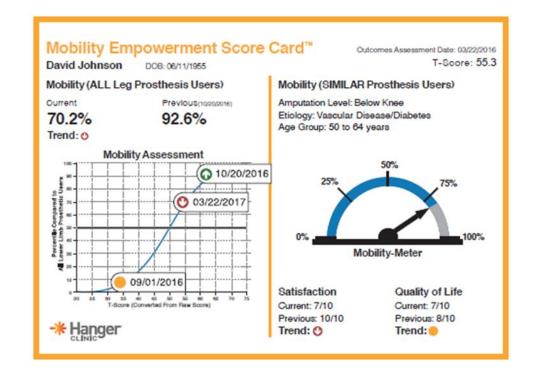


Case Studies: Transforming Patient Care

Ongoing Monitoring Enables Early Intervention

Sample Case Study:

- Age: 50 to 64
- Etiology: Vascular Disease/Diabetes
- What are the trends?
- Declines in high mobility patient following illness



How outcomes data can help?



Assessment can help direct care to increase mobility



Peer comparisons helps to manage patient expectations

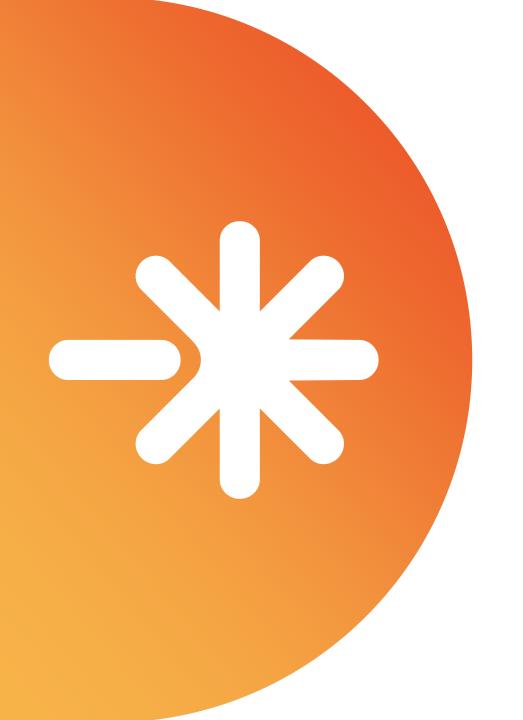


Ongoing monitoring enables early intervention



Mobility tracking directs efficient care plan





Research



Research Insights



Our landmark research helps us develop insights-based clinical programs designed to improve patient outcomes, set a national standard of care, and drive the O&P profession forward.

MOBILITY ANALYSIS OF AMPUTEES (MAAT)

Led by our Department of Clinical & Scientific Affairs, the MAAT series is one of the largest multicenter retrospective analyses of mobility among lower limb prosthetic patients evaluating satisfaction, quality of life, comorbid health conditions, and prosthetic component choices.

MAAT 1:

Maximizing mobility through prosthetic rehabilitation positively impacts quality of life and satisfaction.

Prosthetics and Orthotics American Journ International, Oct. 2017 Rehabilitati

MAAT 2:

Comorbidities including diabetes, osteoporosis, heart failure, COPD, and obesity, do not significantly impact prosthetic mobility.

American Journal of Physical and Rehabilitation, Nov. 2018

MAAT 3:

Microprocessor knee technology improves mobility for above-knee limb loss patients and cuts in half the functional gap between below-knee and above-knee users.

Assistive Technology The Official Journal of RESNA, Dec. 2018

MAAT 4:

A classification tree analysis was developed to effectively predict the probability of a lower limb prosthetic patient's functional potential and inform K-Level designation.

Disability and Rehabilitation: Assistive Technology, Feb. 2019

MAAT 5:

Prosthetic ankle-foot selection directly impacts functional mobility for patients with an amputation due to diabetes and/or vascular disease.

Journal of Rehabilitation and Assistive Technologies Engineering, Feb. 2019

MAAT 6:

Patients with vascular disease / diabetes who remained actively engaged in prosthetic rehabilitation as far out as 7 years postamputation experienced high levels of quality of life, satisfaction, and sustained mobility.

Journal of Prosthetics and Orthotics, Feb. 2020

Questions and Answers



5

- 1. Margolis DJ, Malay DS, Hoffstad OJ, Leonard CE, MaCurdy T, López de Nava K, Tan Y, Molina T, Siegel KL. Prevalence of diabetes, diabetic foot ulcer, and lower extremity amputation among Medicare beneficiaries, 2006 to 2008: Data Points #1. SourceData Points Publication Series [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2011 Feb 17
- 2. Centers for Disease Control and Prevention. National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States, 2014. Atlanta, GA: U.S. Department of Health and Human Services; 2014.
- 3. National Diabetes Data Group. Diabetes in America. Vol. 2. Bethesda, MD: National Institutes of Health; 1995. NIH Pub. No. 95–1468.
- 4. Reiber GE, Ledous WE. Epidemiology of diabetic foot ulcers and amputations: evidence for prevention. In: Williams R, Herman W, Kinmonth A-L, et al., eds. The evidence base for diabetes care. London: John Wiley & Sons; 2002. p. 641-665.
- 5. Murdoch DP, Armstrong DG, Dacus JB, Laughlin TJ, Morgan CB, Lavery LA. The natural history of great toe amputations. JFoot Ankle Surg 1997;36:204-8.
- 6. Dillingham TR, Pezzin LE, Shore AD. Reamputation, mortality, and health care costs among persons with dysvascular lower-limb amputations. Arch Phys Med Rehabil 2005;86:480-6.
- 7. Thomas SR, Perkins JM, Magee TR, Galland RB. Transmetatarsal amputation: an 8-year experience. Ann R Coll Surg Engl. 2001 May; 83(3): 164–166.
- 8. Gershater MA, Löndahl M, Nyberg P, Larsson J, Thörne J, Eneroth M, Apelqvist J. Complexity of factors related to outcome of neuropathic and neuroischaemic/ischaemic diabetic foot ulcers: a cohort study. Diabetologia. 2009 Mar;52(3):398-407.

- 9. Hafner BJ, Morgan SJ, Askew RL, Salem R. Psychometric properties of self-report outcome measures for prosthetic applications. American Academy of Orthotists & Prosthetists (AAOP) 42nd Annual Meeting and Scientific Symposium, Orlando, FL, March 9-12, 2016.
- 10. Amtmann D, Kim J, Chung H, Park R, Salem R, and Hafner BJ. Comparison of Computerized Adaptive Testing and Fixed-Length Short Forms of the Prosthetic Limb Users Survey of Mobility (PLUS-M™). International Society for Quality of Life Research (ISOQOL) 22nd Annual Conference. Vancouver, Canada, October 21-24, 2015.
- 11. Gaunaurd I, Gailey R, Salem R, Hafner B. Construct validity of the Prosthetic Limb Users Survey of Mobility (PLUS-M). Proceedings of the 15th World Congress of the International Society of Prosthetics and Orthotics, Lyon, France, June 22-25, 2015.
- 12. Spaulding S, Gaunaurd I, Gailey R, Morgan S, Amtmann D, Salem R, Hafner B. Prosthetists' confidence administering outcome measures. Proceedings of the 15th World Congress of the International Society of Prosthetics and Orthotics, Lyon, France, June 22-25, 2015.
- 13. Hafner B, Morgan S, Askew R. Reliability of self-reported outcome measures in people with lower limb loss: implications to clinical care and research. Proceedings of the 15th World Congress of the International Society of Prosthetics and Orthotics, Lyon, France, June 22-25, 2015.
- 14. Morgan S, Askew R, Hafner B. Equivalence of electronic and paper administration for four self-report instruments used in prosthetic clinical care. Proceedings of the 15th World Congress of the International Society of Prosthetics and Orthotics, Lyon, France, June 22-25, 2015.
- 15. Morgan SJ, Kelly VE, Salem R, Hafner BJ. Self-reported cognitive concerns in people with lower limb loss. Proceedings of the American Academy of Orthotists & Prosthetists (AAOP) 41th Annual Meeting and Scientific Symposium, New Orleans, LA, February 18-21, 2015.



- 16. Amtmann D, Abrahamson D, Morgan S, Salem R, Askew R, Gailey R, Gaunaurd I, Kajlich A, Hafner B. The PLUS-M: item bank of mobility for prosthetic limb users. Proceedings of the ISOQOL 20th Annual Conference, Berlin, Germany, October 15-18, 2014
- 17. Hafner BJ, Amtmann D, Abrahamson DC, Morgan SJ, Kajlich AJ, Salem R. Normative PEQ-MS and ABC scores among persons with lower limb loss. American Academy of Orthotists & Prosthetists (AAOP) 39th Annual Meeting and Scientific Symposium, Orlando, FL, February 20-23, 2013.
- 18. Hafner BJ, Amtmann D, Abrahamson DC, Morgan SJ, Kajlich AJ, Salem R. Patient Reported Outcome Measurement Information System profiles of persons with lower limb loss. American Academy of Orthotists & Prosthetists (AAOP) 39th Annual Meeting and Scientific Symposium, Orlando, FL, February 20-23, 2013.
- 19. Morgan SJ, Abrahamson DC, Gailey RS, Amtmann D, and Hafner BJ. The use of cognitive interviews to evaluate item content in a prosthetic mobility outcome measure. International Society for Prosthetics and Orthotics (ISPO) World Congress, Hyderabad, India, February 4-7, 2013.
- 20. Amtmann D, Askew RL, Abrahamson DC, Morgan SJ, and Hafner BJ. Empirical support for distinct mobility groups of prosthetic users. International Society for Prosthetics and Orthotics (ISPO) World Congress, Hyderabad, India, February 4-7, 2013.
- 21. Abrahamson DC, Morgan SJ, Gailey RS, Amtmann D, and Hafner BJ. The use of focus groups to aid in the development of a mobility outcome measure. International Society for Prosthetics and Orthotics (ISPO) World Congress, Hyderabad, India, February 4-7, 2013.

- 22. Hafner BJ, Amtmann D, Abrahamson DC, Morgan SJ, Kajlich AJ, Salem R. Large-scale administration of shortened versions of the Prosthesis-Evaluation Questionnaire Mobility Subscale (PEQ-MS) and Activities Specific Balance Confidence Scale (ABC) in persons with lower limb loss. International Society for Prosthetics and Orthotics (ISPO) World Congress, Hyderabad, India, February 4-7, 2013.
- 23. Hafner BJ, Amtmann D, Abrahamson DC, Morgan SJ, Kajlich AJ, Salem R. Health profiles of persons with lower limb loss. International Society for Prosthetics and Orthotics (ISPO) World Congress, Hyderabad, India, February 4-7, 2013.
- 24. Amtmann D, Abrahamson DC, Morgan SJ, Salem R, Askew RL, and Hafner BJ. The development of the PLUS-M, a new measure of mobility for prosthetic limb users. International Society for Prosthetics and Orthotics (ISPO) World Congress, Hyderabad, India, February 4-7, 2013.
- 25. Amtmann D, Abrahamson DA, Morgan S, Salem R, Askew RL, Hafner B. Symptoms and quality of life indicators of persons with lower limb loss. ISOQOL 19th Annual Conference, Budapest, Hungary, October 24-27, 2012.
- 26. Abrahamson DC, Morgan SJ, Amtmann D, Hafner BJ: Understanding the effect of the environment on mobility with a lower limb prosthesis 38th Annual Meeting of the American Academy of Orthotists & Prosthetists (AAOP), Atlanta, GA, March 21-24, 2012

- 27. Ziegler-Graham K, MacKenzie EJ, Ephraim PL, Travison TG, Brookmeyer R. Estimating the Prevalence of Limb Loss in the United States: 2005 to 2050. Archives of Physical Medicine and Rehabilitation, 2008;89(3):422-9.
- 28. Owings M, Kozak LJ, National Center for Health S. Ambulatory and Inpatient Procedures in the United States, 1996. Hyattsville, Md.: U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics; 1998.
- 29. HCUP Nationwide Inpatient Sample (NIS). Healthcare Cost and Utilization Project (HCUP). Rockville, MD: Agency for Healthcare Research and Quality; 2009.
- 30. Fisher ES, Goodman DC, Chandra A. Disparities in Health and Health Care among Medicare Beneficiaries: A Brief Report of the Dartmouth Atlas Project. Robert Wood Johnson Foundation 2008.
- 31. Robbins JM, Strauss G, Aron D, Long J, Kuba J, Kaplan Y. Mortality Rates and Diabetic Foot Ulcers. Journal of the American Podiatric Medical Association 2008 November 1, 2008;98(6):489-93.
- 32. Pandian G, Hamid F, Hammond M. Rehabilitation of the Patient with Peripheral Vascular Disease and Diabetic Foot Problems. In: DeLisa JA, Gans BM, editors. Philadelphia: Lippincott-Raven; 1998.
- 33. Morgan SJ, Amtmann D, Abrahamson DC, Kajlich AJ, Hafner BJ. Use of cognitive interviews in the development of the PLUS-M item bank. Qual Life Res, 2014; 23(6):1767-75. (Pubmed link) (direct link to article)
- 34. McNutt. Can We Prevent Most Amputations? The Amputee Coalition says "Yes!". Amputee Coalition, http://www.amputee-coalition.org/resources/can-we-prevent-most/ 2010 Feb; V. 20. Issue 1.

